

Att. Dkt. No: IFT-5726  
BBE No.: 113959-023

1615  
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the Patent Application Of:  
James E. Kipp et al.

For: MICROPRECIPITATION METHOD  
FOR PREPARING SUBMICRON  
SUSPENSIONS

Serial No.: 09/874,499

Filed: June 5, 2001

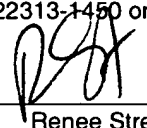
Examiner: Simon J. Oh

Art Unit: 1615

Conf. No.: 6158

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2<sup>nd</sup> SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. 1.97, a list of documents is disclosed on the attached form PTO-1449 that may be material to the examination of this application. A copy of each of the documents is enclosed herewith for the Examiner's consideration. No inference should be drawn that the attached list represents a comprehensive investigation of the prior art; that any or all are pertinent to the invention; or that any apparatus disclosed is equivalent to the subject invention.

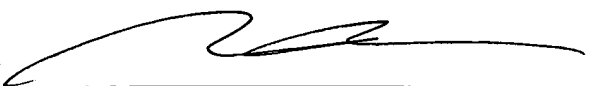
Applicants do not believe any additional fee is due in connection with this 2<sup>nd</sup> Supplemental Information Disclosure Statement, however, the Commissioner is hereby authorized to change any additional fees (or credit any overpayment) to Deposit Account No. 02-1818.

The identified patents and documents do not suggest or make obvious the claimed invention. Hence, allowance of the pending application is respectfully requested.

Respectfully submitted,  
BELL, BOYD & LLOYD LLC

Date: May 7, 2004

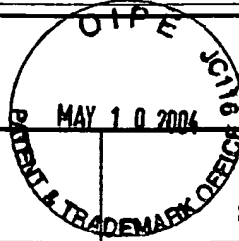
BY

  
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**TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT**  
(Under 37 CFR 1.97(b) or 1.97(c))

Docket No.  
**IFT-5726**

In Re Application Of: **James E. Kipp et al.**



Serial No.  
**09/874,499**

Filing Date  
**June 5, 2001**

Examiner  
**Simon J. Oh**

Group Art Unit  
**1615**

Title: **MICROPRECIPITATION METHOD FOR PREPARING SUBMICRON SUSPENSIONS**

Address to:  
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P.O. Box 1450  
Alexandria, VA 22313-1450**

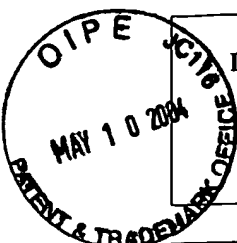
**37 CFR 1.97(b)**

1. ☒ The Information Disclosure Statement submitted herewith is being filed within three months of the filing of a national application other than a continued prosecution application under 37 CFR 1.53(d); within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; before the mailing of a first Office Action on the merits, or before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

**37 CFR 1.97(c)**

2. ☐ The Information Disclosure Statement submitted herewith is being filed after the period specified in 37 CFR 1.97(b), provided that the Information Disclosure Statement is filed before the mailing date of a Final Action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an Action that otherwise closes prosecution in the application, and is accompanied by one of:
- ☐ the statement specified in 37 CFR 1.97(e);
- OR**
- ☐ the fee set forth in 37 CFR 1.17(p).

<b>TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT</b> (Under 37 CFR 1.97(b) or 1.97(c))			Docket No. <b>IFT-5726</b>	
In Re Application: <b>James E. Kipp et al.</b>				
Serial No. <b>09/874,499</b>	Filing Date <b>June 5, 2001</b>	Examiner <b>Simon J. Oh</b>	Group Art Unit <b>1615</b>	
<b>MICROPRECIPITATION METHOD FOR PREPARING SUBMICRON SUSPENSIONS</b>				
<b>Payment of Fee</b> (Only complete if Applicant elects to pay the fee set forth in 37 CFR 1.17(p))				
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<p>*This certificate may only be used if paying by deposit account.</p> <div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="width: 45%;">             _____            Signature         </div> <div style="width: 45%;">           Dated:    <b>May 7, 2004</b> </div> </div> <p> <b>Robert M. Barrett, Reg. No. 30, 142</b>  <b>BELL, BOYD &amp; LLOYD LLC</b>  <b>P.O. Box 1135</b>  <b>Chicago, IL 60690-1135</b>  <b>Tel: (312) 807-4204</b> </p>				
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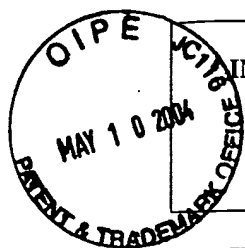


<b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b> (use several sheets if necessary)  PTO Form 1449	Atty Docket No. IFT-5726	Application No. 09/874,499
	Applicant Kipp et al.	
	Filing Date June 5, 2001	Group 1615

U.S. PATENT DOCUMENTS							
Examiner's Initials		Document Number	Publication Date	Inventor	Class	Subclass	Filing Date If Appropriate

FOREIGN PATENT DOCUMENTS								
Examiner's Initials		Document Number	Publication Date	Country	Class	Subclass	Translation	
							Yes	No
		EP 0169 618 B2	10 Nov 1993	EP			X	
		EP 0207 134 B1	17 Aug 1994	EP			X	
		EP 0275 796 B2	6 Sept 1995	EP				X
		EP 0349 428 B1	20 Jan 1993	EP			X	
		EP 0372 070 B1	15 Jan 1997	EP			X	
		EP 0377 477 B1	24 Mar 1993	EP			X	
		EP 0379 379 B1	18 Jan 1990	EP			X	
		EP 0498 482 B1	8 Sept 1999	EP			X	
		EP 0499 299 B1	16 Aug 2000	EP			X	
		EP 0517 565 B1	18 Oct 2000	EP			X	
		EP 0535 534 A1	7 Apr 1993	EP			X	
		EP 0577 215 A1	1 May 1994	EP			X	
		EP 0600 532 A2 EP 0600 532 A3	8 June 1994	EP			X	
		EP 0601 618 A2 EP 0601 618 A3	15 June 1994	EP			X	
		EP 0601 619 A2 EP 0601 619 A3	15 June 1994	EP			X	
		EP 0602 700 A2 EP 0602 700 A3	22 June 1994	EP			X	
		EP 0602 702 A1	22 June 1994	EP			X	

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							Yes	No
		EP 0605 024 A2 EP 0605 024 A3	6 July 1994	EP			X	
		EP 0644 755 B1	19 Mar 1997	EP			X	
		EP 0720 471 B1	18 Apr 2001	EP			X	
		EP 0730 406 B1	8 July 1998	EP			X	
		EP 0752 245 B1	22 May 2002	EP			X	
		EP 0754 034 B1	22 Jan 1997	EP			X	
		EP 0788 350 B1	27 Feb 2002	EP			X	
		EP 0804 162 B1	5 Sept 2001	EP			X	
		EP 0808 154 B1	20 Dec 2000	EP			X	
		EP 0812 187 B1	2 May 2003	EP			X	
		EP 0820 300 B1	2 Apr. 1996	EP			X	
		EP 0828 479 B1	24 Oct 2001	EP			X	
		EP 0831 770 B1	16 Aug 2000	EP			X	
		EP 0832 569 A2 EP 0832 569 B1	1 Apr 1998 26 Nov 2003	EP			X	
		EP 0988 863 A3	9 Aug 2000	EP			X	
		EP 1012 204 B1	29 Jan 2003	EP			X	
		EP 1105 109 B1	23 Apr 2003	EP			X	
		EP 1156 788 B1	15 Jan 2003	EP			X	
		EP 1210 942 A2	5 June 2002	EP			X	
		WO 85/00011 A1	3 Jan 1985	PCT			X	
		WO 86/03676 A1	3 July 1986	PCT			X	
		WO 89/11850 A1	14 Dec 1989	PCT			X	
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		WO 90/15593 A1	27 Dec 1990	PCT			X	
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		WO 91/12794 A1	5 Sept 1991	PCT			X	
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		WO 95/05164 A1	23 Feb 1995	PCT			X	
		WO 95/27482 A1	19 Oct 1995	PCT			X	
		WO 96/00567 A1	11 Jan 1996	PCT			X	

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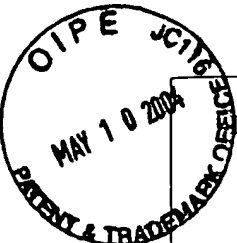
**FOREIGN PATENT DOCUMENTS**

Examiner's Initials	Document Number	Publication Date	Country	Class	Subclass	Translation	
						Yes	No
	WO 96/14833 A1	23 May 1996	PCT			X	
	WO 96/20698 A2	11 July 1996	PCT			X	
	WO 96/24336 A1	15 Aug 1996	PCT			X	
	WO 96/24340 A1	15 Aug 1996	PCT			X	
	WO 96/25150 A1	22 Aug 1996	PCT			X	
	WO 96/25152 A1	22 Aug 1996	PCT			X	
	WO 96/25918 A1	28 Aug 1996	PCT			X	
	WO 96/31231 A1	10 Oct 1996	PCT			X	
	WO 97/03657 A1	19 July 1996	PCT			X	
	WO 97/14407 A1	24 Apr 1997	PCT			X	
	WO 97/30695 A1	28 Aug 1997	PCT			X	
	WO 97/36611 A1	9 Oct 1997	PCT			X	
	WO 97/41837 A2	13 Nov 1997	PCT			X	
	WO 97/44014 A1	27 Nov 1997	PCT			X	
	WO 98/07410 A1	26 Feb 1998	PCT			X	
	WO 98/07414 A1	26 Feb 1998	PCT			X	
	WO 98/14174 A1	9 Apr 1998	PCT			X	
	WO 98/14180 A1	9 Apr 1998	PCT			X	
	WO 98/35666 A1	20 Aug 1998	PCT			X	
	WO 98/57967 A1	23 Dec 1998	PCT			X	
	WO 99/00113 A1	7 Jan 1999	PCT			X	
	WO 99/02665 A1	21 Jan 1999	PCT			X	
	WO 99/03450 A1	29 Jan 1999	PCT			X	
	WO 99/16443 A1	8 Apr 1999	PCT			X	
	WO 99/29316 A1	17 June 1999	PCT			X	
	WO 99/30833 A1	24 June 1999	PCT			X	
	WO 99/32156 A2	1 July 1999	PCT			X	
	WO 99/33467 A1	8 July 1999	PCT			X	
	WO 99/38493 A1	5 Aug 1999	PCT			X	
	WO 99/49846 A2	7 Oct 1999	PCT			X	
	WO 99/49848 A1	7 Oct 1999	PCT			X	
	WO 99/61001 A1	2 Dec 1999	PCT			X	
	WO 99/65469 A3	23 Dec 1999	PCT			X	
	WO 00/09096 B1	24 Feb 2000	PCT			X	
	WO 00/12124 A1	9 Mar 2000	PCT			X	

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							Yes	No
		WO 00/12125 A1	9 Mar 2000	PCT			X	
		WO 00/18374 A1	6 Apr 2000	PCT			X	
		WO 00/27363 A1	18 May 2000	PCT			X	
		WO 00/30615 A1	2 June 2000	PCT			X	
		WO 00/30616 A1	2 June 2000	PCT			X	
		WO 00/37050 A1	29 June 2000	PCT			X	
		WO 00/40220 A1	13 July 2000	PCT			X	
		WO 00/51572 B1	8 Sept 2000	PCT			X	
		WO 00/71079 A2	30 Nov 2000	PCT			X	
		WO 01/12155 A1	22 Feb 2001	PCT			X	
		WO 01/17546 A1	15 Mar 2001	PCT			X	
		WO 01/26635 A2	19 Apr 2001	PCT			X	
		WO 01/62374 A2	30 Aug 2001	PCT			X	
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		WO 01/87264 A2	22 Nov 2001	PCT			X	
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		WO 02/24163 A1	28 Mar 2002	PCT			X	
		WO 02/43702 A2	6 June 2002	PCT			X	
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		WO 02/60411 A2	8 Aug 2002	PCT			X	
		WO 02/72070 A1	19 Sept 2002	PCT			X	
		WO 02/72071 A1	19 Sept 2002	PCT			X	
		WO 02/74282 A1	26 Sept 2002	PCT			X	
		WO 02/80883 A2	17 Oct 2002	PCT			X	
		WO 02/89773 A2	14 Nov 2002	PCT			X	
		WO 03/26611 A2 WO 03/26611 A3	3 Apr 2003	PCT			X	
		WO 03/35031 A1	1 May 2003	PCT			X	

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	Applicant Kipp et al.	
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Examiner's Initials	OTHER DOCUMENTS (Including Author Title Date Pertinent Pages Etc.)
	Davis et al., "Pulmonary Perfusion Imaging: Acute Toxicity and Safety Factors as a Function of Particle Size", J.Nucl Med., Vol. 19 (1978), pp. 1209-1213.
	Schroeder et al., "Physiological Effects of Subvisible Microspheres Administered Intravenously to Beagle Dogs", Journal of Pharmaceutical Sciences, Vol. 67, No. 4, April 1978, pp. 508-512.
	Yokel et al., "Acute Toxicity of Latex Microspheres", Toxicity Letters, Vol. 9 (1981), pp. 165-170.
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	B. Sjostrom et al., "Preparation Of Submicron Drug Particles In Lecithin-Stabilized O/W Emulsions I. Model Studies Of The Precipitation Of Cholesteryl Acetate", Int. J. Pharm., 88 (1992) pp 53-62.
	B. Sjostrom et al., "A Method For The Preparation Of Submicron Particles Of Sparingly Water-Soluble Drugs By Precipitation In Oil-In-Water Emulsions. II: Influence Of The Emulsifier, The Solvent And The Drug Substance", J. Pharm. Sci., 82(6), (1992) pp 584-589.
	Duncker and Reichelt, "Effects of the Pharmaceutical Cosolvent hydroxypropyl-beta-cyclodextrin on Porcine Corneal Endothelium", Graefe's Archive for Clinical and Experimental Ophthalmology (Germany), 236/5 (1998), pp. 380-389.
	Volchek and Dellen, "Anaphylaxis to Intravenous Cyclosporine and Tolerance to Oral Cyclosporine, Case Report and Review", Annals of Allergy, Asthma, and Immunology, 80 (1998), pp. 159-163.
	Singla et al., "Paclitaxel and its Formulations", International Journal of Pharmaceutics, 235/1-2 (2002), pp. 179-192.
	B. Sjostrom et al., "The Formation of Submicron Organic Particles by Precipitation in an Emulsion", J.Dispersion Science and Technology, 15(1), 89-117 (1994).
	Avanti Polar Lipids, Inc., website printout, www.avantilipids.com, "Synthetic Products - Functionalized Phospholipids: Lipids for Conjugation of Proteins/Peptides/Drugs to Liposomes" (7 pgs), March 2003.
	Avanti Polar Lipids, Inc., website printout, www.avantilipids.com, "Polymer and Polymerizable Lipids: Functionalized PEG Lipids" (3 pgs), March 2003.
	Avanti Polar Lipids, Inc., website printout, www.avantilipids.com, "Polymer and Polymerizable Lipids: Poly(ethylene glycol)-Lipid Conjugates" (8 pgs) , March 2003.

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